

General Information	
EudraVigilance Local Report Number	EU-EC-10008822508
Sender Type	Health professional
Sender's Organisation	PFIZER S.R.L.
Type of Report	Spontaneous
Primary source country	Non-European Economic Area
Reporter's qualification	Healthcare Professional
Case serious?	Yes

Patient		
Age Group	Age Group (as per reporter)	Sex
0-1 Month		Male

Reaction / Event			
MedDRA LLT	Duration	Outcome	Seriousness ¹
Meconium aspiration		Unknown	other
Unknown cause of death		Fatal	death.
Maternal exposure during pregnancy, second trimester		Fatal	death., other
Premature birth		Unknown	other

Drug Information					
Role ²	Drug	Duration	Dose	Units in Interval	Action taken
S	TOZINAMERAN - TOZINAMERAN			Total	Not applicable
S	TOZINAMERAN - TOZINAMERAN	1.0 Days		Total	Not applicable
C	- LORATADINE		10.0 mg	Days	
C	- CRISABOROLE				

Drug Information (cont.)					
Info ³	Drug	Indication	Pharm. Form	Route of Admin.	Parent Route of Admin.
	TOZINAMERAN - TOZINAMERAN	COVID-19 immunisation		Transplacental	Intramuscular
	TOZINAMERAN - TOZINAMERAN	COVID-19 immunisation		Transplacental	Intramuscular
	- LORATADINE	Allergy			
	- CRISABOROLE	Atopic dermatitis		Transplacental	Topical

Information Concerning the Parent for a Parent-Child/Foetus Report

Parent	
Age	Sex
18-64 Years	Female

1 Seriousness: **death**=results in death; **life threat.**=life threatening; **hospital.**=requires hospitalization/prolongation of hospitalization; **disability** =results in disability/incapacity; **congen.**=congenital anomaly/birth defect; **other**=other medically important information; **(blank)**=non-serious

2 Drug role: **S**=suspect; **C**=concomitant; **I**=interacting; **N**=not administered

3 Additional Information on Drug: **1**=Counterfeit; **2**= Overdose; **3**=Drug taken by the father; **4**=Drug taken beyond expiry date; **5**=Batch and lot tested and found within specifications; **6**=Batch and lot tested and found not within specifications; **7**=Medication error; **8**=Misuse; **9**=Abuse; **10** =Occupational exposure; **11**=Off label use; **(blank)**=no additional information